

REMARKS

The present invention relates to an immunological latex turbidimetry method and reagent.

Preliminarily, it is appreciated that at page 2 of the Office Action of November 17, 2005, the Examiner has indicated withdrawal of the previous objections and rejections. However, in the present Office Action, claims 1, 4, 6, and 9 have been rejected under 35 U.S.C. § 103 as being unpatentable over Hunter et al in view of Shinoda et al. Furthermore, claims 5 and 10 have been rejected under 35 U.S.C. § 103 based on Hunter et al in view of Shinoda et al, further in view of Nakase et al. The Examiner had recognized that the Masson et al reference did not anticipate the present invention because the BSA was carried on latex particle and not protease treated as set forth in the claims, but the Examiner found the Hunter et al and Shinoda et al references as being more pertinent.

In the present Amendment, Applicants have noted that the present invention uses the protease-treated fragmentated bovine serum albumin, and claims 1 and 6 have been amended to include such further specific recitation. This amendment is support by the disclosure in the specification, e.g., at page 4, lines 15 - 19. Applicants respectfully submit, as will be explained below in more detail, that in view of the amendments to independent claims 1 and 6, all of the presently pending claims 1, 4 - 6, and 9 - 10 are unobvious and patentable over the Hunter et al, Shinoda et al, and Nakase et al references that were applied in the present Office Action.

Below, Applicants first discuss a characteristic feature of the present invention, and then compare the present invention vis-à-vis the newly cited prior art.

Rejection under 35 U.S.C. §103(a) over Hunter et al. in view of Shinoda et al.

Characteristic features of the present invention

One of the important features of the present invention resides in the aspect that a "protease-treated bovine serum albumin (BSA)" is used as an agent for reducing a non-specific reaction in an immunological latex turbidimetry analysis (see page 3, lines 7-3 from the bottom of the present specification). The protease-treated BSA is a fragmentated BSA (page 4, line 18), which may be prepared by treating BSA with a protease (page 4, the last line to page 5, line 2).

Hunter et al. reference

Regarding the newly-cited Hunter et al reference, in the Office Action it was stated that:

"Hunter et al. teach agglutination procedures to measure antibody-antigen binding. In one embodiment, pepsin treated antibodies are coupled to BSA (protease treated BSA) and use to measure antigen interaction via agglutination." (page 3, lines 5-7 of the Office Action)

With respect to the recitation "pepsin treated antibodies are coupled to BSA (protease treated BSA)", the Hunter et al states that:

"Pepsin F(ab)2 fragments of human red cell rabbit antibody were

"coupled to bovine serum albumin" (page 363, lines 27-28).

As is clear from the above description, the Hunter et al. reference discloses the complex of "BSA" *per se* (i.e., intact BSA) and "pepsin treated antibodies", and the use of BSA *per se*, but does not disclose or suggest the fragmentated BSA according to the presently claimed invention.

Shinoda et al. reference

The Shinoda et al. reference discloses an agglutination test to measure cryptococcal antigens, as pointed by the Examiner. However, the Shinoda et al. reference does not disclose or suggest the fragmentated BSA according to the presently claimed invention.

As described above, neither of the Hunter et al or Shinoda et al references disclose or suggest the fragmentated BSA used in accordance with the presently claimed invention. Therefore, Applicants respectfully submit that the present invention, characterized by the use of the protease-treated fragmentated BSA, would not be obvious from the combination of the Hunter et al. reference and the Shinoda et al. reference cited against claims 1, 4, 6, and 9.

Nakase et al. reference

As pointed out by the Examiner, the Nakase et al. reference discloses that the addition of BSA to streptolysin O stabilizes streptolysin O. However, the Nakase et al. reference does not disclose or suggest the fragmentated BSA accordingly to the presently claimed invention.

Therefore, even if the disclosure of Nakase et al is further added to the disclosure of the Hunter et al and Shinoda et al references, there is no bases for a person of ordinary skill in the art to arrive at the presently claimed invention.

Accordingly, it is respectfully submitted that the rejections of claims 1, 4 - 6, and 9 - 10 under 35 U.S.C. § 103 should now be withdrawn.

In view of the above, reconsideration and allowance of claims 1, 5, 6, 6, 9 and 10 of the present application are now believed to be in order, and such actions are hereby earnestly solicited.

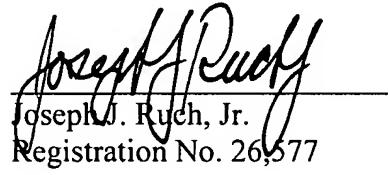
If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C. telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111
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Respectfully submitted,



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